

UNDERSTANDING TYPES OF STUDIES:

EXPLORING CLINICAL TRIALS AND REAL-WORLD EVIDENCE



Medicines can be studied in multiple ways. Asking your doctor about different medical study results may help you feel more confident about talking to your doctor about treatment decisions.

How will treatment affect my life?
Is this treatment safe?
What are my options?
Can I continue to work?

CLINICAL TRIALS

A clinical trial is a type of research study that can be used to help us understand how a medicine works. The FDA uses clinical trial results when deciding whether to approve new medicines or not.

There are several types of clinical trials. One common type is the *randomized controlled trial (RCT)*. When it comes to studying a new or existing treatment, RCTs are thought to be the gold standard.

REAL-WORLD STUDIES

WHAT ARE REAL-WORLD STUDIES?

After medicines are approved, other studies can be done with people in the “real world.” These can teach us about how well the treatment works, or even what patients say about how they feel on treatment.

SEEING A FULLER PICTURE

Randomized Controlled Trials (RCTs)

- Often compare treatments by randomly selecting the study participants who receive the drug
- Are the “gold standard” when it comes to testing new treatments or new uses for approved treatments
- Are conducted in a controlled setting, often before a treatment is approved for use
- Tell us if a treatment is safe and effective
- Study a carefully selected group of patients
- Analyze data collected in a rigorous scientific study

Real-World Studies

- Complement RCTs, do not replace them
- Are conducted after approval, once more people have taken the treatment
- Show how a treatment works on actual patients in a real-world setting (safety data may not be collected)
- Study a broad group of patients who use the treatment in real life
- Discover sources of information like:



Medical
Records



Insurance
Claims



Online
Apps

HERE ARE SOME QUESTIONS TO HELP YOU GET STARTED WITH YOUR OWN LIST:

- How have these treatment options been studied?
- What was the experience of others who received these treatments?
- Why do you think this treatment may be best for me?
- What can I expect from this treatment?



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